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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,351	07/30/2001	Makoto Asashima	31671-173644	1990

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,351	Applicant(s) ASASHIMA ET AL.
	Examiner Janice Li	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

Claims 3-5, 7-11, and 15-17 have been amended by the Preliminary amendment. Claims 1-17 are pending in the application and under current examination.

Priority

This application claims benefit of priority to Japan H11-021077, filed January 29, 1999.

Information Disclosure Statement

The information disclosure statement filed July 30, 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language (PTO-1449/AA, AC, AD, AE, AF). They have been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 13-17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. These claims depend from claim 12, which is drawn to an evaluation method for *in vitro* induced organ. However, claims 13-17 only recite the characteristics of the organs

being evaluated but not the method steps of evaluation, thus, fail to further limit the subject matter of the base claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided.

Claims 1-10 are directed to a preparation method of organs induced *in vitro* and functioning *in vivo* upon transplantation. The method comprises culturing the organ to a certain stage, which is determined by the expression of genomic DNA markers; in a

preferred embodiment, the organ is induced from ectoderm region which has been cut off from the blastula in the presence of a member of TGF-β family, preferably activin, and additionally retinoic acid. The induced organ is selected from the group consisting of kidney, heart, pancreas, liver, enteric canal, notochord, skeletal muscle, leukocyte, erythrocyte and lymphocyte, wherein the organ could be used for embryo transplantation. Given the broadest reasonable interpretation, the claims encompass a preparation method for *any* organ from *any* type of vertebrate animals including human under an *unspecified* condition. In a preferred embodiment culturing *any* organ from the *ectoderm* in the presence of the members of TGF-βs.

In view of the guidance provided, the specification teaches *in vitro* cultivation of *Xenopus* embryo ectoderm treated with activin and retinoic acid, which induced differentiation of pronephros, when transplanted the pronephros into an embryo in which pronephros primordium has been removed, the *in vitro* induced pronephros functioned *in vivo* (page 4, first paragraph). The specification further teaches that in the presence of activin, the animal cap (cut-off tissue ectoderm of blastula) from *Xenopus* differentiated into the heart, skeletal muscle, notochord, and leukocyte tissue; additionally, in further presence of cytokines IL-11, SCF, or RA, the animal cap could also differentiated to lymphocyte, erythrocyte, and pronephric tubule, respectively (figure 2).

In view of the state of the art and levels of the skill in the art of embryonic stem cell development, it is still under development and highly unpredictable. At the time the application was filed, *Burdon et al* (Cells Tis Org 1999;165:131-34) teach "THE

MOLECULAR BASIS OF THE SELF-RENEWING PLURIPOTENT PHENOTYPE REMAINS ILL-DEFINED. THE RELATIONSHIP BETWEEN FACTORS THAT INFLUENCE EMBRYONIC STEM CELLS PROPAGATION IN VITRO AND MECHANISMS OF STEM CELL REGULATION OPERATIVE IN THE EMBRYO IS ALSO UNCERTAIN" (see abstract). *Hardy et al* (J Endocrinol 2002;172:221-36) teach that human development is regulated by embryonically and maternally derived growth factors of various kinds at different stages of the embryo development. These growth factors and their receptors would influence the rate of embryo development, the proportion of embryos developing to the blastocytst stage, blastocyst cell number, metabolism and apoptosis by ways of atocrine, paracrine, and endocrine pathways that may operate within the embryo and between the embryo and the reproductive tract (see abstract and entire document). From the teachings of the skilled in the art and the specification, the development of different organs involves different cytokines, receptors, and the environment of a maternal host. One cannot extrapolate from disclosed condition for the development of pronephrons of a xenopus to that of any organ of any vertebrate animal, because the cytokine ligands, cellular receptors, the complicity of maternal environments differ among different organs of a vertebrate, and among different classes of vertebrates such as amphibian, bird, fish, and mammal. The cytokines that function in certain stage of a *Xenopus* may not be effective in fish or human. IL-11 is required for the development of lymphocytes but not that of leukocytes, for example.

In addition, organs such as heart or kidney are known to be derived from mesoderm (see EB reference). Although applicants demonstrated that the ectoderm region of *Xenopus* could differentiation to pronephron under certain conditions, the

specification fails to teach whether organs such as heart could also be differentiated from the animal cap, what such conditions are.

The claims are drawn to using genomic markers to determine the stage of organ development, the gene expression in various stages of the development in different organs are bound to be distinct among different classes of vertebrate, the specification fails to teach which of genes expressed at what stage in which organ of the which vertebrate could be used as a determining factor for amphibians, birds, bony fish, chimaera chondrichthian, mammal, reptile, etc., one skilled in the art could not practice the claimed invention without first carrying out extensive experimentation to determine the parameters for practice the invention, i.e. which genome DNA could be used for stage markers for a particular organ in a particular vertebrate animal.

The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). It is noted that in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 38 USPQ 189 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule:

"IT IS WELL SETTLED THAT IN CASES INVOLVING CHEMICALS AND CHEMICAL COMPOUNDS, WHICH DIFFER RADICALLY IN THEIR PROPERTIES IT MUST APPEAR IN AN APPLICANT'S SPECIFICATION EITHER BY THE ENUMERATION OF A SUFFICIENT NUMBER OF THE MEMBERS OF A GROUP OR BY OTHER APPROPRIATE LANGUAGE, THAT THE CHEMICALS OR CHEMICAL COMBINATIONS INCLUDED IN THE CLAIMS ARE CAPABLE OF ACCOMPLISHING THE DESIRED RESULT."

Accordingly, in view of the quantity of experimentation necessary to determine the parameters for achieving *in vitro* induced, stage-specific organ preparation, in particular for obtaining organs functioning *in vivo* when transplanted into a recipient of the same species, the lack of guidance provided by the specification as well as the absence of working examples with regard to *any* organ from *any* species of a vertebrate, it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in

possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement;* Federal Register/ Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 11 recites "an in vitro induced organ for transplantation characterized in that the organ is prepared by the method of in vitro induced organ according to claim 1". Given the broadest reasonable interpretation, the claim embraces any organ from any species that is obtained by in vitro induction. The claim essentially does not place any limit to the organs claimed. However, the organs taught in the specification are from *Xenopus*, which are limited to those derived from ectoderm region, and the pronephric tubule is the only one shown to be functioning in the embryo transplantation.

As discussed in the Enablement section above, the specification fails to provide an enabling disclosure for the broad class of organs induced *in vitro*, thus, it fails to provide an adequate written description for the broad class of organs that would function *in vivo* upon transplantation. The Revised Interim Guidelines state "THE CLAIMED INVENTION AS A WHOLE MAY NOT BE ADEQUATELY DESCRIBED IF THE CLAIMS REQUIRE AN ESSENTIAL OR CRITICAL ELEMENT WHICH IS NOT ADEQUATELY DESCRIBED IN THE SPECIFICATION AND WHICH IS NOT CONVENTIONAL IN THE ART" (Column 3, page 71434), "WHEN THERE IS SUBSTANTIAL VARIATION WITHIN THE GENUS, ONE MUST DESCRIBE A SUFFICIENT VARIETY OF SPECIES TO REFLECT THE VARIATION WITHIN THE GENUS", "IN AN UNPREDICTABLE ART, ADEQUATE WRITTEN DESCRIPTION OF A GENUS WHICH EMBRACES WIDELY VARIANT SPECIES CANNOT BE ACHIEVED BY DISCLOSING ONLY ONE SPECIES WITHIN THE GENUS" (Column 2, page 71436). Considering the potential numbers of organs encompassed by the claims, in view of the variations in cytokines,

receptors, and the complex mechanisms of embryonic development, the disclosed organs are not the representative species of the genus.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of *all* organs induced *in vitro* and functioning *in vivo* upon transplantation. Therefore, only the described *Xenopus* organs induced from ectoderm region of the blastula in the presence of activin meet the written description provision of 35 U.S.C. §112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, and 8-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3, and 8-10 are vague and indefinite. The claims are directed to a method for preparation of organs, however, only the end product but not active and positive steps are provided in the method. Method claims need not recite all operating

details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

Claims 12-17 are vague and indefinite. The claims are directed to a method for evaluation of *in vitro* induced organs; however, steps of evaluation have not been recited beyond the transplantation. Method claims need not recite all operating details but should at least recite positive, active steps so that the claims will set out and circumscribe a particular area with a reasonable degree of precision and particularity and make clear what subject matter that claims encompass as well as make clear the subject matter from which others would be precluded, *Ex parte Erlich*, 3 USPQ2d 1011 at 6.

Claim 8 is vague and indefinite because it recites a Markush group improperly. See MPEP 2173.05 (h).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 10, 11 are rejected under 35 U.S.C. 102(e) as being anticipated by *Slavkin et al* (US 4,672,032).

These claims are drawn to a method for *in vitro* induced organ functioning *in vivo* upon transplantation to a recipient of the same species, wherein the organ could be used for transplantation, wherein the organ is cultured to a certain stage corresponding to the recipient, where the recipient is a vertebrate. The claim or specification fails to define the term "induce" or limiting the term "stage", thus, the claims embrace any organ culture in any stage of the ontogeny, including matured organ.

Slavkin et al teach a method for *in vitro* induced formation of dental enamel crystals as restorative material for use in mammals (see abstract). Thus, *Slavkin et al* anticipate the instant claims.

Claims 1, 2, and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by *Stice et al* (US 2001/0039667).

Stice et al teach a method for *in vitro* induced ungulate embryos and offspring, and teach that the resulting fetuses and embryos may be used for transplantation therapy (see abstract). They go on to teach that the differentiated cells and tissues may be derived from ectoderm (0098, page 8). Thus, *Stice et al* anticipate the instant claims.

Claims 1-6, and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by *Asashima et al* (Proc Natl Acad Sci USA 1991 Aug;88:6511-14).

These claims are drawn to a method for *in vitro* induced organ functioning *in vivo* upon transplantation, wherein the organ is cultured to a certain stage corresponding to the recipient, wherein the certain stage is determined by the expression of a genomic marker. In a preferred embodiment, the organ is induced from ectoderm region which has been cut off from the blastula; wherein the *in vitro* induction takes place in the presence of TGF-beta family, particularly activin; wherein the organ is selected from the group consisting of notochord, muscle, etc.; wherein the organ recipient is the same species, an embryo, and belong to vertebrate. Claim 11 is drawn to an *in vitro* induced organ.

Asashima et al teach in vitro induced organs, such as notochord, muscle, mesenchyme, and epidermis (fig. 2). The organs are induced from early *Xenopuse* (vertebrate) animal-cap cells (ectoderm of a stage 9 blastula), wherein the cell explants are cultured in the presence of activin (EDF, left column of page 6512). *Asashima et al* teach that different genes may express at different stages of the embryo development, such as Xar9 (paragraph bridging columns in page 6513). Thus, *Asashima et al* anticipate the instant claims.

Claims 1, 2, 4-6, and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by *Ariizumi et al* (Int J Dev Biol 1991;35:407-14).

Ariizumi et al teach *in vitro* induced organs, such as notochord, muscle, mesenchyme, blood cells, and epidermis (fig. 3). The organs are induced from presumed ectoderm region of *Xenopuse* (see Materials and Methods on page 412), wherein the cell explants are cultured in the presence of activin (fig. 1). Thus, *Ariizumi et al* anticipate the instant claims.

Claims 1, 2, 4-6, and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by *Asashima et al* (Dev Biol 1990;198:330-335, PTO-1449/AG).

Asashima et al teach that treatment of amphibian explants with activin A led to differentiation of mesodermal derivatives such as notochord, muscle, mesenchyme, and blood cells (abstract, figs. 1, 3, table 1). Thus, *Asashima et al* anticipate the instant claims.

Claims 1-6, and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by *Yokotal et al* (Biochem Biophy Res Communications 1995 Feb;207:1-7), as evidenced by *Asashima et al* (Dev Biol 1990;198:330-335, PTO-1449/AG).

Yokotal et al teach that treatment of explants from the animal hemisphere of *Xenopus* embryos with activin A led to the expression of different genes at different stage (abstract and Discussion). Although, *Yokotal et al* do not teach which organs the explants would differentiate to, they would have differentiated to notochord, muscle, mesenchyme, and blood cells because it is the intrinsic property of these explants as evidenced by *Asashima et al.* Thus, *Yokotal et al* anticipate the instant claims.

Claims 1, 2, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by *Agren et al* (Diabetes 1980;29:64-69).

Agren et al teach a method of culturing human fetal pancreas *in vitro* and these cultivated organs could be used for transplantation in attempts to treat human diabetes (see abstract). Thus, *Agren et al* anticipate the instant claims.

Claims 1, 2, 5, 7, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by *Morales et al* (Arch Biochem Biophy).

Morales et al teach a method of culturing cartilage *in vitro* in the presence of TGF-β family members and retinoic acid. Thus, *Morales et al* anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Hullett et al* (Hum Immunol 1997;52:127-37), or *Andersen et al* (Acta Ophthalmol 1988;66:313-7), in view of *Asashima et al* (Proc Natl Acad Sci USA 1991;88:6511-14).

These claims are drawn to an evaluation method of *in vitro* induced organ by transplanting said organ into a living organism.

Hullett et al teach a method evaluating cultured organs in hyperbaric oxygen before transplantation to the survival of an allograft. *Andersen et al* teach an evaluation method for organs in transplantation, i.e. the influence of donor age and post mortem time on corneal graft survival. *Hullett et al* or *Andersen et al* do not teach to evaluate the organs induced *in vitro* from ectoderm region.

Asashima et al teach *in vitro* induced organs, such as notochord, muscle, mesenchyme, and epidermis (fig. 2). The organs are induced from early *Xenopuse* (vertebrate) animal-cap cells (ectoderm of a stage 9 blastula), wherein the cell explants are cultured in the presence of activin (EDF, left column of page 6512). *Asashima et al* teach that different genes may express at different stages of the embryo development, such as Xar9 (paragraph bridging columns in page 6513).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the methods taught by *Hullett et al* and *Andersen et al* in evaluating the organs taught by *Asashima et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to use the method for evaluation of any cultured organ intended for use in transplantation because it is the reliable way to find out whether the cultured organ could function properly *in vivo*. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
April 3, 2002

JAMES KETTER
PRIMARY EXAMINER